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Regulation of Dietary Supplements: Five Years of DSHEA

LAURA A. W. KHATCHERESSIAN*

There is no alternative medicine. There is only scientifically proven evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking.¹

I. INTRODUCTION

On October 25, 1994, President Clinton signed into law the Dietary Supplement Health and Education Act (DSHEA),² passed unanimously by both houses of Congress. This law radically changed the regulatory landscape for the sale and labeling of dietary supplements, restricting the Food and Drug Administration's (FDA's) authority in certain ways, and encouraging the sale of dietary supplements, including vitamins, minerals, herbs, botanicals, and amino acids.

This article examines DSHEA and discusses current FDA attempts to regulate dietary supplements. Part II provides a brief background and discusses FDA's concerns and attitude toward dietary supplements before the passage of DSHEA. Part III discusses recent congressional actions that have influenced FDA's ability to regulate dietary supplements: passage of the Nutrition Labeling and Education Act (NLEA), the moratorium imposed on use of NLEA to restrict dietary supplement labels, and passage of DSHEA in 1994. Part IV describes the regulatory changes brought about by DSHEA.

Part V reviews concerns stemming from the recent growth in the dietary supplement industry and from the regulatory framework currently in place. Concerns about consumer safety and the efficacy of dietary supplements are discussed, and some recent reports of contamination of dietary supplements are reviewed. Part VI chronicles FDA actions since DSHEA, and discusses how FDA is attempting to regulate dietary supplements under DSHEA. The recent Cholestin® decision is analyzed, as is the U.S. Court of Appeals for the D.C. Circuit's ruling that the First Amendment restricts FDA's ability to prevent manufacturers from placing certain health claims on their supplements.

Finally, part VII offers a proposal that would increase consumer knowledge of dietary supplement safety and efficacy.³ In the current situation, benign but useless products are shelved beside, and labeled similarly to, both useful products with real health benefits and products that can be harmful. Even the thoughtful consumer is hard-pressed to distinguish one product from another. Unfortunately, there seems little hope that Congress will change the situation, absent some catastrophic public health event.

II. FDA CONCERNS AND REGULATION BEFORE DSHEA

FDA's concern about dietary supplements dates back to the 1938 passage of the Federal Food, Drug, and Cosmetic Act (FDCA),⁴ although the level and focus of that

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¹ Phil B. Fontanarosa, M.D. & George D. Lundberg, M.D., *Alternative Medicine Meets Science*, JAMA, Nov. 11, 1998, at 1618-19.

² Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 note (1994)).

³ The author views the current state of the law with considerable concern, and views the panoply of dietary supplements currently available on the market with considerable skepticism.

⁴ Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq.).

concern has changed over time.⁵ Soon after the FDCA was passed, FDA established detailed labeling requirements for foods marketed for "special dietary uses."⁶ These rules remained effective until 1962 when FDA published regulations that proposed to set minimum and maximum levels for dietary supplements, but withdrew them in the face of consumer protest.⁷ FDA then attempted to regulate excessive dosages of vitamins as drugs through adjudication; this was an approach foreclosed by Congress.⁸ In the late 1970s, FDA again attempted to regulate high-level dosage vitamins as drugs through adjudication, this time focusing on the toxic impacts of the products.⁹ The federal courts, however, were not receptive to this approach, nor to the alternative approach of regulating supplements as food additives.¹⁰

As the number, availability of, and consumer interest in dietary supplements has grown in the United States in recent decades,¹¹ FDA has become more concerned about and interested in how to regulate these products. In 1993, FDA made it clear that the agency viewed its mission as ensuring that the products are safe and that "claims made for their use are scientifically supported, truthful, not misleading, and otherwise in accord with applicable legal standards."¹²

The agency is concerned with both "direct"¹³ and "indirect"¹⁴ effects. In addition, health care professionals are concerned about the interactions of supplements with prescription drugs.¹⁵ This should be considered in light of the recent information that many consumers do not inform physicians about their use of dietary supplements.¹⁶ Furthermore, FDA and the Federal Trade Commission (FTC) are interested in the

⁵ The following brief review of historical regulatory efforts by FDA is not intended to be comprehensive. Rather, it is intended to give a sense of the type of efforts made by FDA in the past to regulate dietary supplements.

⁶ PETER HUTT & RICHARD MERRILL, *FOOD & DRUG LAW CASES AND MATERIALS* 212-21 (2d ed. 1991).

⁷ FDA focused on vitamin and mineral supplements at that time. The concern over herbals and amino acids is relatively recent. *See, e.g.*, HUTT & MERRILL, *supra* note 6, at 212-21; S. REP. NO. 103-410, at 15 (1994).

⁸ In 1976, Congress passed the Health Research and Health Services Amendments (sometimes referred to as the Proxmire/Rogers amendments) to the FDCA, Pub. L. No. 94-278, 90 Stat. 401 (codified in scattered sections of 21 U.S.C. §§ 301 et seq.) Title V of these amendments restricted FDA's authority over vitamin and minerals, and added § 411 to the FDCA. 21 U.S.C. § 350 (as amended). That section prohibits FDA from establishing maximum limits on the potency of vitamins or minerals, and forbids FDA from classifying a vitamin or mineral product as a drug "solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful." *Id.* § 350(a)(1)(B).

⁹ *See* National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325 (2d Cir. 1977) (rejecting FDA's classification of high doses of vitamins A and D as drugs). *But see* Nutrilab, Inc. v. Schweiker, 713 F.3d 335 (7th Cir. 1983) (accepting FDA's classification of "starch blockers" as drugs).

¹⁰ *See, e.g.*, United States v. Two Plastic Drums, 984 F.2d 814 (7th Cir. 1993) (rejecting FDA's argument that encapsulated black currant oil could be a "food additive," when the single active ingredient of the "food" was the black currant oil itself); United States v. 29 Cartons of an Article of Food, 987 F.2d 33 (1st Cir. 1993) (reaching same conclusion on similar facts and characterizing FDA's interpretation of the FDCA as "nonsensical").

¹¹ *See, e.g.*, Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690-91 (June 18, 1993) (noting the increased use and availability of dietary supplements).

¹² *Id.* at 33,691.

¹³ *Id.* (defining direct effects as "those adverse health effects directly attributable to the components of dietary supplement products").

¹⁴ *Id.* (defining indirect effects as the problems that may arise "if the use of a supplement product delays the diagnosis or treatment of a health disorder").

¹⁵ *See, e.g.*, Wayne B. Jonas, M.D., *Alternative Medicine — Learning from the Past, Examining the Present, Advancing to the Future*, JAMA, Nov. 11, 1998, at 1616-18 (noting that "[f]ifteen million Americans are taking high-dose vitamins or herbal preparations along with prescription drugs, thereby risking adverse effects from unknown interactions").

¹⁶ A recent study indicates that while use of alternative medicine (including treatment with dietary supplements, such as high doses of vitamins or herbal remedies) and visits to alternative medicine practitioners have increased markedly in recent years, only 38.5% of those who use alternative therapies discussed them with their physician. Fontanarosa & Lundberg, *supra* note 1, at 1618-19; *see also* Yitzhak Beigel et al., *A Leading Question*, NEW ENG. J. MED., 827-30, n.4 (Sept. 17, 1998) (indicating that up to 72% of patients who use "unconventional treatments" do not inform their physicians).

prevention of consumer fraud, and are anxious to prevent a health-conscious public from spending money on products that, even if benign, are not necessary or useful for good health.¹⁷

While many of the ingredients in dietary supplements appear to be harmless or even helpful, there are products that pose hazards. FDA's concern in the early 1990s was galvanized by a 1989 outbreak of at least 1500 cases of eosinophilia myalgia syndrome, resulting in thirty-eight deaths, that was caused by the use of supplements containing the amino acid L-tryptophan.¹⁸ FDA's current concerns are prompted by additional examples of harm resulting from dietary supplement use. For example, from 1993 to 1997 fifteen deaths and approximately 400 "adverse reactions" were attributed to the herbal dietary supplement ephedra.¹⁹

FDA's attempts to classify dietary supplements in such a way (as food additives or as drugs) as to ensure some type of premarket approval of their safety, and possibly of their efficacy, were not wholly successful. These efforts, however, drew the attention of the dietary supplement industry and Congress.

III. CONGRESSIONAL ACTION AND REACTION

FDA's attempt to regulate dietary supplements in the 1980s was influenced by the L-tryptophan calamity and agency concern over labels that made unsubstantiated claims of health benefits.²⁰ Congressional passage of the NLEA²¹ provided a new avenue of possibilities for FDA to regulate claims made by dietary supplements. The NLEA allowed FDA to pass regulations requiring that specific information, including the serving size, amount of certain nutrients, vitamins, or minerals, and information relating to those substances, be placed on the labels of food products.²²

The NLEA directed FDA to use a standard of "significant scientific agreement" to decide whether foods could make "health claims."²³ The NLEA, however, specifically allowed FDA to recommend a different standard and approval procedure for supplements.²⁴ In December 1991, FDA proposed implementing regulations that opted to use the "significant scientific agreement" standard for dietary supplements, as well as for foods.²⁵ Using this standard, FDA rejected all but one health claim for supplements.²⁶

In response to intense advocacy by the dietary supplement industry, Congress passed a one-year moratorium on the application of the NLEA provisions to dietary

¹⁷ See, e.g., Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (1998) (visited Nov. 18, 1998) <www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>.

¹⁸ See 58 Fed. Reg. at 33,691.

¹⁹ See, e.g., Peter A. Vignuolo, *The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994*, 21 SETON HALL LEGIS. J. 200, 200-02 (1997). Evidence of reactions to ephedra, an herbal extract that has been marketed "as an alternative, legal method of obtaining a drug-like high," convinced FDA to warn consumers against taking the product and propose rules for dietary supplements containing ephedrine alkaloids. *Id.* at 201; *Products That Consumers Inquire About* (visited Mar. 24, 1999), available at <vm.cfsan.fda.gov/~dms/ds-prod.html> (citing Dietary Supplements Containing Ephedrine Alkaloids, 62 Fed. Reg. 30,678 (to be codified at 21 C.F.R. 111) (June 4, 1997)).

²⁰ See Vignuolo, *supra* note 19, at 211, nn. 69-71.

²¹ Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. §§ 301 note, 321, 337, 343, 343 notes, 343-1, 343-1 note, 345, 371).

²² 21 U.S.C. § 343 (NLEA § 2).

²³ 21 U.S.C. § 343(r)(3)(B)(i) (NLEA § 3(a)).

²⁴ NLEA § 3(b), 104 Stat. 2353, 2361.

²⁵ S. REP. NO. 103-410 at 15.

²⁶ *Id.*

supplements in 1992.²⁷ In May 1991, however, FDA created a Task Force to "review the agency's regulatory program for dietary supplements and to recommend improvements."²⁸ The Task Force completed its report in May 1992 and submitted a recommendation that at least some dietary supplements be regulated as drugs.²⁹

The report and recommendations, however, were mooted largely by the efforts in Congress to change the regulation of dietary supplements from 1993 to 1994. A substantial lobbying effort led by the dietary supplement industry,³⁰ that continued after the NLEA moratorium was enacted, eventually resulted in the passage of DSHEA. Congress obviously was influenced by the grassroots lobbying effort of the dietary supplement-consuming public (who were encouraged and, arguably, misinformed by the dietary supplement industry).³¹ Congress also was angered by FDA's strained interpretations of the FDCA in the black currant oil cases,³² and by FDA's lack of speed in approving health claims for folic acid.³³ A U.S. Senate report on DSHEA argued that "FDA has tried to 'protect' the public against 'unsafe' products for which there is no evidence that the product is unsafe," while acting to "restrict the information that the public may receive about dietary supplements."³⁴

IV. DSHEA: MAJOR CHANGES IN THE REGULATORY LANDSCAPE

DSHEA was touted by congressional promoters as balancing the consumer interest in good health and nutrition against the government interest "in guaranteeing the quality and safety of foods and products available to consumers"³⁵ by providing adequate and accurate information on dietary supplements so that consumers could make informed choices, and by ensuring that unsafe products could be removed from the marketplace.³⁶

DSHEA made some important changes in the regulatory framework. The three most important aspects of DSHEA were: 1) providing a clear definition of a "dietary supplement"; 2) changing the rules surrounding the labeling of dietary supplements; and 3) shifting the burden of proof about a product's safety from the manufacturer to FDA.

A. Broadening the Definition of Dietary Supplement

DSHEA defined "dietary supplement" broadly to include any non-tobacco product "intended to supplement the diet" that includes a vitamin, mineral, herb (or "other botanical"), amino acid, "dietary substance for use by man to supplement the diet by increasing the total dietary intake," or a "concentrate, metabolite, constituent, extract, or combination of" any preceding substances.³⁷ As discussed below, unless a dietary

²⁷ See Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491 (codified in scattered sections of 21 U.S.C. §§ 301 et seq.).

²⁸ 58 Fed. Reg. at 33,691.

²⁹ *Id.* at 33,697 (citing findings of Task Force that the "primary intended use" of certain amino acid products "is for therapeutic rather than nutritional purposes").

³⁰ See, e.g., Vignuolo, *supra* note 19, at 215-20; Dante E.A. Ramos, *Vitamin Makers Try a Dose of Lobbying*, 25 NAT'L HEALTH J. 1879 (1993).

³¹ See Vignuolo, *supra* note 19, at 215-20 (arguing that the industry informed consumers that Congress was considering a complete restriction of all dietary supplements).

³² See *supra* note 10.

³³ S. REP. NO. 103-410, at 16.

³⁴ *Id.*

³⁵ See, e.g., Statement by President William J. Clinton upon signing S. 784 (Oct. 25, 1994), *reprinted in* 1994 U.S.C.C.A.N. § 3523-1.

³⁶ *Id.*

³⁷ 21 U.S.C. § 321(ff) (DSHEA § 3(a)).

supplement is "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease," it is a food.³⁸

The definition explicitly includes articles approved as new drugs that, prior to that approval, were "marketed as a dietary supplement or as a food," unless FDA has issued a regulation finding that the article was adulterated.³⁹ The term "dietary supplement" does not include "an article that is approved as a new drug,"⁴⁰ if it was not present in the food supply as a food or dietary supplement prior to its approval. Interpretation of this language, and particularly the definition of "article," recently became crucial in a case where FDA attempted to classify a dietary supplement as a drug whose active ingredient chemically is identical to the active ingredient in an approved prescription drug.⁴¹

Displaying its disapproval of FDA's posture in the black currant oil cases, Congress excluded dietary supplements from the definition of a food additive.⁴² Thus, under the current definition, supplements are foods or drugs, based on their claims and labeling. Congress, however, carved out specific exemptions from normal labeling rules for dietary supplements.

B. Narrowing "Labeling" to Exclude Point-of-Sale Promotional Materials

Before DSHEA, FDA held the position that "labeling" of dietary supplements included not only the claims printed on the actual product or its label, but also any "other written, printed, or graphic matter"⁴³ accompanying the product. Under this definition, FDA could regulate any articles or materials touting the supplement's health benefits, as long as the material "accompanied" the product. With DSHEA, however, Congress changed this.

Section 5 of DSHEA specifically exempts from "labeling" any "publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety."⁴⁴ The exemption does require the publication not to be false or misleading, not to promote a particular brand of a dietary supplement, to be displayed separately from the product itself, and to be "displayed or presented . . . so as to present a balanced view of the available scientific information of a dietary supplement."⁴⁵

This section effectively removed the possibility that FDA could regulate a supplement as a drug based on claims made in materials accompanying the product that the substance was useful in the cure, mitigation, treatment, or prevention of any disease. The clause provides that the materials must present a "balanced view of the available scientific information"⁴⁶ about a substance; however, it is unclear how much weight that provision carries. If the only "available scientific information" is non-clinical

³⁸ 21 U.S.C. §§ 321(ff)(3), 321(g). As discussed *infra*, a dietary supplement may make structure/function claims. See *id.* § 341(r)(6).

³⁹ *Id.* § 321(ff)(3)(A).

⁴⁰ *Id.* § 321(ff)(3)(B).

⁴¹ See *infra* notes 82-92, and accompanying text.

⁴² 21 U.S.C. § 321(s) (DSHEA § 3(b)).

⁴³ See 21 U.S.C. § 321(m) (general definition of labeling); see also 58 Fed. Reg. at 33,690.

⁴⁴ 21 U.S.C. § 343-2(a) (DSHEA § 5).

⁴⁵ *Id.* Congress also required that the publication "not have appended to it any information by sticker or any other method." *Id.* § 343-2(a)(5).

⁴⁶ *Id.* § 343-2(a)(3).

trials performed by the manufacturers themselves, it seems consistent with the plain language of the statute that no other information need be provided, even though the studies done may not represent a scientific consensus.

DSHEA also detailed when the labels of dietary supplements would violate the law. The labels of dietary supplements may make health claims describing "general well-being from consumption of a nutrient or dietary ingredient,"⁴⁷ claiming an impact of a supplement on the "structure or function" of the body, or claiming a benefit relating to a classical nutrient deficiency disease (subject to certain conditions), as long as the manufacturer of the product has "substantiation" (which DSHEA neither defined nor required to be submitted to FDA⁴⁸) that the claim "is truthful and not misleading."⁴⁹ In addition, the manufacturer must print on the label the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."⁵⁰ Compliance with these provisions ensures that the supplement will not be regulated as a drug.⁵¹

FDA opted to regulate NLEA health claims "for both foods and dietary supplements in the same way."⁵² Thus, a food or dietary supplement manufacturer wishing to characterize the relationship of a nutrient listed on its label to a disease or health-related condition must seek and obtain FDA's approval. That approval will be granted only if there is "significant scientific agreement . . . based on the totality of publicly available scientific evidence"⁵³ that the claim is supported.⁵⁴

C. *Shifting the Burden of Proving Safety, or Lack Thereof, to FDA*

The third important aspect of DSHEA was to shift the burden of proving safety from the manufacturer to FDA. If a supplement was considered a food additive or a new drug, the manufacturer would be required to prove the supplement was safe (and, if a drug, effective for its intended use) — either by showing that the substance was generally regarded as safe or by providing some clinical trials and studies showing that the substance was safe under conditions of use. Because DSHEA defines dietary supplements as a subset of foods, they are not required yet to undergo a premarket approval process. If FDA is uncertain of a supplement's safety and wishes to remove it from the market, it affirmatively must prove that the product would be harmful if taken as recommended.⁵⁵

⁴⁷ *Id.* § 343(r)(6) (DSHEA § 6).

⁴⁸ See, e.g., Paula Kurtzweil, *An FDA Guide to Dietary Supplements* (visited Mar. 24, 1999), available at <vm.cfsan.fda.gov/~dms/fdsupp.html> (noting that while a manufacturer "must be able to substantiate its claim, it does not have to share the substantiation with FDA or make it publicly available"). Without any objective analysis of manufacturer "substantiation," it is unclear if the requirement of substantiation is an empty one.

⁴⁹ 21 U.S.C. § 343(r)(6) (DSHEA § 6).

⁵⁰ 21 U.S.C. § 343(r)(6)(C).

⁵¹ *Id.* § 321(g)(D) (noting in part that a dietary supplement "for which a claim, subject to [the provisions regulating misbranding under the FDCA], is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim").

⁵² See 59 Fed. Reg. at 426 (codified at 21 C.F.R. § 101.14).

⁵³ 21 U.S.C. § 343(r) (DSHEA § 6(B)); see also 21 U.S.C. §§ 343(r)(3); 343(r)(5)(D) (exempting dietary supplements from the process required for foods). FDA has approved several health claims for foods, such as the statements that calcium helps to prevent osteoporosis and that folic acid helps pregnant women prevent their children from being born with neural tube defects. Katherine E. Harris, *Law Exempts Diet Supplements From Labeling Rules* (last modified Mar. 10, 1999), <www.legislate.com/xp/p-special/i-1999031001/a-9210866071/article.view> (quoting FDA spokeswoman).

⁵⁴ The apparent conflict between the language of DSHEA and FDA's regulations regarding "health claims" is discussed later in this paper.

⁵⁵ 21 U.S.C. § 342(f)(A) (noting that a dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury"). Alternatively, if FDA determines that a product poses an "imminent

V. IMPACTS AND PROBLEMS OF DSHEA

The results of DSHEA are difficult to quantify, but it is clear that there has been an explosion in the marketing and use of dietary supplements that could not have been possible without the loosened regulatory structure of the Act. Americans spent approximately twelve billion dollars for all dietary supplements in 1997, and surveys indicate that "more than half of the U.S. adult population" uses them.⁵⁶ Loosened oversight under DSHEA has allowed small businesses to start selling substances such as androstenedione (the hormone taken by baseball star Mark McGuire) in violation of the relaxed DSHEA rules.⁵⁷ Today, FDA estimates that there are 25,000 to 30,000 supplement products available.⁵⁸ The growth in some herbal supplements is phenomenal.⁵⁹

Five years of DSHEA have brought to light three major areas of concern: 1) problems involving definitions of "dietary supplements;" 2) problems involving the claims made by supplement manufacturers; and 3) problems involving the purity and consistency of the supplements.

A. Definitional Concerns

The definition of "dietary supplement," understood in 1994 to be broad, has turned out to include not only the vitamins, minerals, and herbs that Congress may have had in mind when it passed DSHEA, but also substances that are sold as prescription drugs in other countries, and even in the United States.⁶⁰ While these products fall

hazard to public safety," FDA immediately may remove it from the market, but then must hold a proceeding to affirm or negate that decision. *Id.* § 342(f)(C). FDA also has authority to prohibit the marketing of a new dietary ingredient "for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury." *Id.* § 342(f)(B). The term "new dietary ingredient," however, does not reach most dietary supplements. 21 U.S.C. § 350b defines "new dietary ingredient" such that only those supplements for which the dietary ingredients were not present in the food supply as an article used for food or there is some "history of use or other evidence of safety" for the new dietary ingredient are "adulterated" under § 342(f). Furthermore, the term "new dietary ingredient" only applies to those ingredients not marketed in the United States before passage of the DSHEA in October 1994. *Id.* § 350b(c).

⁵⁶ Katherine E. Harris, *Issue Focus: Lawmakers Push Door Open for Dietary Supplements* (last modified Mar. 10, 1999) <www.legislate.com/xp/p-special/i-current/a-921085778/article.view> (noting that "sales of nutritional supplements are up almost 30 percent since 1995"); Jane E. Henney, M.D., *Statement of Jane E. Henney, M.D., Commissioner of FDA, Before the Committee on Government Reform, U.S. House of Representatives*, at 2 (Mar. 25, 1999), <www.fda.gov/ola/dietary.html>.

⁵⁷ See, e.g., Rochelle Sharpe, *Staking Claims: One Effect of A Law on Diet Supplements is Leaner Regulation*, WALL ST. J., Jan. 27, 1999, at 1. This describes one businessman's start-up company, that sells androstenedione under claims that it is "safe," "proven," "FDA legal," that it "reverses male aging" and "burns fat, builds muscle and boosts strength, energy and sex drive." *Id.* The seller states that he has no concerns about the safety or efficiency of his product containing androstenedione, because he has "done research" consisting of his personal experience with the product and "reading up on the substance over the Internet for a week." *Id.* He recommends one 100 mg. tablet per day. In contrast, a medical doctor who has given patients androstenedione limits his patients to one or two 100 mg. tablets per week, monitors the patients' reactions, and requires them to undergo medical testing if they wish to increase their dosage. Doctors have concerns that the substance adversely could affect the prostate gland or the heart. *Id.*

⁵⁸ *National Public Radio: Dietary Supplements*, (Morning Edition broadcast, Mar. 30, 1999) (visited Apr. 1, 1999) <www.npr.org/programs/morning/dietsupplements/html>.

⁵⁹ See generally Legi-Slate, *Alternative Medicine: America's Top 10 Herbal Remedies* (visited Mar. 22, 1999) <www.legislate.com/ftplib/diettab.htm> (reporting on the increase in sales of herbal products); Dana Canedy, *Real Medicine or Medicine Show? Growth of Herbal Remedy Sales Raises Issues About Value*, N.Y. TIMES, July 23, 1998, at D1.

⁶⁰ *National Public Radio: Dietary Supplements*, *supra* note 58; see also text *infra*, accompanying notes 82-89 (discussing the availability of Cholestol[®], a dietary supplement containing the same substance as is available in the prescription drug Mevacor[®]).

under the broad definition of "dietary supplements," there are health care concerns about use of these products by the public without physician supervision.⁶¹

In addition, supplements that are not marketed as prescription drugs in other countries or in the United States have had negative effects on consumers, raising the question of whether the existing definition covers only products that do not require premarket screening for safety. For example, Gamma-Butyrolactone, marketed as a sleep aid and a body-building supplement, has caused symptoms similar to intoxication in at least one case and seizures in another.⁶² FDA asked manufacturers to pull products containing this substance from their shelves after the products caused at least fifty-five cases of serious illnesses and one death.⁶³ Other studies show reason for concern about the safety of other widely promoted herbal remedies.⁶⁴

FDA informed Congress that the number of reported adverse reactions to dietary supplements is increasing.⁶⁵ News reports indicate that serious adverse reactions to readily available supplements are a problem.⁶⁶ DSHEA's suggestion that the fact that a substance was marketed, in some form, in the United States as a food or dietary supplement before October 1994, gives sufficient evidence of a substance's safety is, in short, becoming increasingly doubtful.⁶⁷

B. Consumer Use of Dietary Supplements: To Cure as Well as to Promote Health

In response to claims made by promoters of these supplements, consumers take supplements not only to "affect the structure and function of the body" or to promote general well-being, but also to treat and prevent diseases. A recent study shows that significant groups of the public believe that supplements can "generally help people with . . . illnesses."⁶⁸ Furthermore, anecdotal evidence suggests that some consumers

⁶¹ Particularly troublesome in light of these concerns is research indicating that up to 72% of patients taking "unconventional treatments" do not inform their physicians. See Yitzhak Beigel et al., *A Leading Question*, NEW ENG. J. MED., Sept. 17, 1998, at 827-30, n.4.

⁶² See Frank Lo Vecchio, D.O. et al., *Butyrolactone-Induced Central Nervous System Depression After Ingestion of RenewTrient*, a "Dietary Supplement," NEW ENG. J. MED., Sept. 17, 1998, at 847-48 (describing case of 36-year-old man stopped by police for driving erratically after ingesting 2 ounces of "RenewTrient" dietary supplement); *National Public Radio: Dietary Supplements*, *supra* note 58 (describing case of woman who took a GBL sleep aid and required hospitalization the following morning for seizures, vomiting, and loss of consciousness).

⁶³ See Harris, *supra* note 56.

⁶⁴ See, e.g., Robert S. Dipaola et al., *Clinical and Biologic Activity of an Estrogenic Herbal Combination (PC-SPES) in Prostate Cancer*, NEW ENG. J. MED., Sept. 17, 1998, at 785-91 (finding that the "use of this unregulated mixture of herbs may confound the results of standard or experimental therapies and may produce clinically significant adverse effects").

⁶⁵ FDA Sees Dietary Supplement Adverse Event Reports Growing, F-D-C REP. ("The Tan Sheet"), Mar. 1, 1999, at 5. FDA noted that "[f]or products for which premarket review programs do not exist, such as dietary supplements and cosmetics, FDA needs information about the safety and usage patterns of such products after they have been approved in order to develop appropriate responses." *Id.* "Dietary supplements are not subject to a premarket safety review or approval by FDA," the agency said. "This means that post-market surveillance, including monitoring of adverse effects associated with marketed products, is the cornerstone of FDA's ability to meet its public health responsibilities for the safety of these products." *Id.*

⁶⁶ See, e.g., *Across the USA: News from Every State*, USA TODAY, Mar. 17, 1999, at 4A (reporting that increasing numbers of young people are reporting to Maryland emergency rooms and poison control centers after ingesting gamma hydroxy butyrate, an "easily available hallucinogenic drug"); Vignuolo, *supra* note 19, at 200 (discussing news coverage of the supplement ephedra that, since 1993, has caused nearly 400 adverse events and 15 deaths).

⁶⁷ See 21 U.S.C. §§ 321(ff), 350b.

⁶⁸ National Public Radio/Kaiser Family Foundation/Kennedy School of Government Survey on Americans and Dietary Supplements, at question 8 (1999) (visited Mar. 29, 1999), <www.npr.org> [hereinafter NPR Poll]. Forty-nine percent of those surveyed believed that supplements could help them with the flu, 61% with a cold, 35% with cancer, 16% with AIDS, 53% with arthritis, and 52% with depression. *Id.*

are using supplements instead of conventional medicine prescribed by physicians to treat diseases such as high blood pressure, high cholesterol, diabetes, and even cancer.⁶⁹ Despite the lengthy legal debate about how the wording of various claims distinguishes a health claim (regulated under NLEA) from a drug claim (regulated by FDA) from a DSHEA statement of nutritional support and well-being (regulated, if at all, by the FTC to protect against fraudulent content),⁷⁰ consumers often perceive claims made by dietary supplement manufacturers as claims that the products will prevent and cure illnesses.⁷¹

C. Purity and Consistency of Dietary Supplements

Finally, there are serious concerns about the purity of dietary supplements. For example, one study of Asian patent medicines found that of 260 medicines available in California retail health food or herbal stores, thirty-two percent contained "undeclared pharmaceuticals or heavy metals," twenty-three products had more than one adulterant, twenty-four products contained amounts of lead of at least ten parts per million, seven percent contained undeclared pharmaceuticals, and fourteen products had labels declaring pharmaceutical ingredients.⁷²

Another report described two patients who reported to emergency rooms with nausea, vomiting, lethargy, irregular heartbeats, chest pressure, shortness of breath, and heart palpitations after taking dietary supplements (marketed for "internal cleansing") that included herbs contaminated with *digitalis lantana*.⁷³ *Digitalis lantana* is a toxin containing cardiac glycosides, which are substances that block electrical impulses to the heart and cause irregular heartbeat in otherwise healthy individuals.⁷⁴ After these cases were brought to the attention of FDA, manufacturers and distributors of the contaminated herbs initiated thirteen voluntary recalls, eight firms received warn-

⁶⁹ *National Public Radio: Dietary Supplements*, *supra* note 58 (interviewing consumer who, against the advice of physicians, is using dietary supplements to treat high blood pressure, cholesterol, and borderline diabetes); see also Max J. Coppes, M.D., Ph.D. et al., *Alternative Therapies for the Treatment of Childhood Cancer*, NEW ENG. J. MED. Sept. 17, 1998, at 846-47 (discussing two child cancer patients whose parents opted to treat them with herbal compounds, in one case Matol Biomune OSF Plus (alleged to "create a synergistic effect on the immune system, resulting in the elevation of natural killer cell activity" and promoted as beneficial for the treatment of a variety of cancers and other diseases), and shark cartilage in the other).

⁷⁰ A statement by Robert McCaleb, a member of the Presidential Commission of Dietary Supplement Labels, captures the confusing lines between these distinctions. Mr. McCaleb states that "[r]egardless of what the consumer believes to be the health impact of a physiological effect of a substance, it is the wording of a claim that determines the type of claim being made." Allison Wright, *FDA's Position on Cholestin Is Misguided, Say Industry Groups*, FOOD LABELING & NUTRITION NEWS, Jan. 15, 1998, at 8-10. Mr. McCaleb goes on to note that "prevents heart disease" is a drug claim, while "may reduce the risk of heart disease" is an NLEA health claim, and "reduces blood cholesterol" is a DSHEA statement of nutritional support. *Id.*

⁷¹ According to the NPR Poll, *supra* note 68, 64% of those surveyed believed that the phrase "supports or boosts the immune system" means that the product will prevent one from getting sick, and 42% believe the same statement indicates that the product will help one who is already sick get better. *Id.* at questions 9-10.

⁷² Richard J. Ko, Pharm. D., Ph.D., *Adulterants in Asian Patent Medicines*, NEW ENG. J. MED., Sept. 17, 1998, at 847; see also Yitzhak Beigel et al., *supra* note 61, at 827-30 (discussing the case of a 43-year-old man hospitalized with unusual symptoms and eventually diagnosed with lead poisoning resulting from his intake of an "Indian plants" herbal remedy, and noting that there have been several reports of lead intoxication from Indian plants in patients with diabetes).

⁷³ Nancy R. Sligman, M.D., M.P.H., et al., *Contamination of Botanical Dietary Supplements by Digitalis Lantana*, NEW ENG. J. MED., Sept. 17, 1998, at 806-11.

⁷⁴ *Id.* Generally, a glycoside is a "compound formed by replacing the hydroxyl (-OH) group of a sugar by another group." BANTAM'S MED. DICTIONARY 185 (rev. ed 1990) "Glycosides found in plants include some pharmacologically important products (such as digitalis)." *Id.*

ing letters from FDA, and FDA issued press releases and posted warnings on its website, telling consumers to avoid these products.⁷⁵

In addition, there are concerns about the consistency of dietary supplements, particularly herbal supplements. Ideally, consumers of botanical products could be confident that the herbal extract pill they are taking has a predictable chemical composition and a consistent amount of the active ingredient. Recent studies of supplements, however, show that consistency varies drastically among widely available brands of the same supplement. For example, St. John's Wort, the herbal remedy publicized for its benefits in counteracting depression, recently was studied by the *Good Housekeeping Institute*, the *Milwaukee Journal Sentinel*, and the *Los Angeles Times*. In the first study, a comparison of six "widely available" St. John's Wort supplements found a "startling lack of consistency" in the quantity of what are believed to be the active ingredients of the herbal remedy.⁷⁶ One manufacturer withdrew its St. John's Wort product from retail pharmacies in Wisconsin after laboratory tests demonstrated that the product contained only 5.3% of the quantity of active ingredient claimed on the label.⁷⁷ Moreover, laboratory tests conducted by the *Los Angeles Times* on ten brands of St. John's Wort showed that three brands had "no more than about half the potency listed on the label," and four more had "less than 90% of the indicated potency."⁷⁸ Other herbal products have been studied with similar results.⁷⁹

VI. FDA ATTEMPTS TO REGULATE UNDER DSHEA

What steps is FDA taking to address these concerns? The following section briefly discusses FDA's actions in recent years regarding the definition of dietary supplements, the claims surrounding those supplements, and the purity and manufacturing practices of the supplements.

A. Definition of Dietary Supplements

As discussed above, the definition of dietary supplements provided by DSHEA is extremely broad. Section 201(ff)(3)(A) of the FDCA explicitly provides that "dietary supplement" includes an "article that is approved as a new drug," as long as that "article" was marketed as a dietary supplement or a food prior to the drug approval.⁸⁰ This provision means that the same substances that are required to go

⁷⁵Sligman, *supra* note 73, at 807. Interestingly enough, the imported raw material that had been contaminated with *digitalis lantana* had been supplied and distributed in the U.S. for approximately two years before the problem was brought to FDA's attention by alert physicians. *Id.* Authors of the *New England Journal of Medicine* article theorized that the medical community, as well as consumers of dietary supplements, may be unaware that they can and should report adverse events associated with dietary supplements to FDA, which has a program (Meditate) specifically designed to investigate such complaints. *Id.* at 810.

⁷⁶Mike Schwartz, *Health and Fitness: The Debate: Some root for herbs, others claim deception*, PRESS-ENTERPRISE (Riverside, Cal.), June 30, 1998, at D1. The study found that the largest amount of hypericin in the manufacturers' recommended doses was 17 times the smallest, and the largest amount of pseudohypericin was 13 times the smallest. *Id.*

⁷⁷Joe Manning & John Fauber, *Aurora Recalls Herbal Pill After Lab Test St. John's Wort Trouble Illustrates Industry's Pitfall*, MILWAUKEE J. SENTINEL, Mar. 11, 1999, at 1, available in 1999 WL 7666562.

⁷⁸Terence Monmaney, *Remedy's U.S. Sales Zoom, but Quality Control Lags; St. John's Wort: Regulatory Vacuum Leaves Doubt About Potency, Effects of Herb Used for Depression*, L.A. TIMES, Aug. 31, 1998, at 1, available in 1998 WL 18869834.

⁷⁹See, e.g., *National Public Radio: Medical: Domestic* (Morning Edition broadcast, Oct. 2, 1997), available in 1997 WL 12823399 (discussing study of ginseng, which found that "of four national brands, two didn't have ginseng at all, and two had ginseng but had been so damaged that it was essentially worthless").

⁸⁰21 U.S.C. § 321(ff)(3)(A).

through the lengthy and costly new drug application (NDA) process, as long as they were previously available in some form in the U.S. food supply, can be sold as dietary supplements as well as drugs.⁸¹

1. *The Cholestin® Decision: Dietary Supplement or Drug?*

This definition posed problems for FDA when Pharmanex began marketing a dietary supplement called Cholestin®. Cholestin®, which is derived from red yeast rice, has been touted for its ability to lower cholesterol. In fact, the red yeast rice in Cholestin® is a natural source of lovastatin,⁸² the active ingredient in a prescription drug, Mevacor®. News coverage of Cholestin® stressed that it was as effective as, and less expensive than, its prescription drug counterpart.⁸³ Cholestin® initially was marketed with labeling “that flamboyantly said this is, in effect, the same as the prescription drug Mevacor.”⁸⁴ After an administrative proceeding to determine the status of this product, in May 1998 FDA declared that Cholestin® was an unapproved drug, and issued a notice barring Pharmanex from importing red yeast rice.⁸⁵ In response, Pharmanex brought an action for preliminary injunction and declaratory judgment against FDA, and was successful in both.⁸⁶

FDA argued that because Cholestin® contains lovastatin, the active ingredient of an FDA-approved prescription drug, Cholestin® is inherently a drug.⁸⁷ Lovastatin, the agency claimed, is an “article” that was approved as a new drug and that was not available in the food supply before that approval. In effect, FDA’s position depended on the definition of the word “article,” and a determination that “article” refers to the lovastatin.⁸⁸ The District Court of Utah rejected this position, finding instead that

⁸¹ *Id.* Articles that were not present in the food supply or against which FDA has issued regulations are not “dietary supplements.” 21 U.S.C. § 321(ff)(3)(B).

⁸² Red yeast rice contains mevinolin, “a natural substance that FDA has determined is chemically indistinguishable from lovastatin.” *Pharmanex v. Shalala*, 1999 WL 80950 *3 (D. Utah 1999).

⁸³ See, e.g., Suzanne Leigh, *Tests Show Dietary Supplement Lower Cholesterol; Rice Product Costs \$20-30 a Month vs. \$120-300 for Prescription Drug*, FORT WORTH STAR-TELEGRAM, Jan. 30, 1999, at 6 (noting that “[t]ests on a product described as a dietary supplement have indicated that it is as effective as expensive prescription drugs for lowering cholesterol”).

⁸⁴ Peter B. Hutt, *Edited Transcript of Remarks of Peter Barton Hutt to NDMA Government Affairs Committee*, Sept. 23, 1998, at 6. After FDA began its investigation of Cholestin®, Pharmanex modified its labeling of the product, removing specific references to mevinolin or lovastatin and limiting its statements of nutritional support to claims such as “promotes healthy cholesterol,” “maintains healthy cholesterol,” “reduces total cholesterol,” “inhibits production of cholesterol in the body,” and “keeps cholesterol in healthy balance.” Allison Wright, *Maker Implements Interim Cholestin Labeling and Marketing Policy*, FOOD LABELING & NUTRITION NEWS, Jan. 8, 1998, at 5.

⁸⁵ *Cholestin Maker Wins Injunction Against FDA Over Red Yeast Imports*, ANDREWS PHARMACEUTICAL LITIG. REP. 3, July 1998, available in WL 14 No.2 ANPHARLR 3; *Cholestin Maker Seeks Preliminary Injunction Barring Reclassification*, ANDREWS PHARMACEUTICAL LITIG. REP. 3, June 1998, available in WL 14 No.1 ANPHARLR 8.

⁸⁶ *Court Ruling on Cholestin is a Setback for FDA in Implementing DSHEA*, FDA WEEK, June 19, 1998, at 1 (noting the court’s preliminary ruling that Cholestin® is a dietary supplement and not a drug); *Pharmanex*, 1999 WL 80950.

⁸⁷ FDA initially had taken the position that the claim that Cholestin® “lowers cholesterol” is a drug claim. They abandoned that position in the administrative decision, however, deferring the claims issue to their April 1998 rulemaking on structure/function claims, discussed *infra*. Hutt, *supra* note 84, at 7.

⁸⁸ FDA’s interpretation was that:

the word “article” as used in the phrase “article approved as a new drug under section 355” in [21 U.S.C.] § 321(ff)(3)(B) can refer to either a finished drug product or any of that drug product’s individual components, depending on the particular circumstances surrounding the manufacture and marketing of the dietary supplement at issue.

Pharmanex, 1999 WL 80950, at *3.

"article" refers not to the lovastatin, but to the finished drug product Mevacor®.⁸⁹ Therefore, unless Cholestin® includes the finished drug product Mevacor®, or was approved as a new drug, it cannot be said that Cholestin® includes an "article approved as a new drug" that was not present in the food supply before such approval.

This decision relied extensively on evidence of congressional intent found in a Senate report explaining that "on occasion, a substance that is properly included as a dietary ingredient in a dietary supplement (food) product may also function as an active ingredient in a drug product."⁹⁰ While it may appear doubtful that Congress actually intended for all substances tested and approved as prescription drugs to be available as dietary supplements, thus bypassing not only the new drug approval process but also the step from prescription drug to over-the-counter (OTC) status, the legislative history can be read to support such a view.⁹¹

Interestingly, the "official" legislative history accompanying DSHEA is less illuminating. It consists of a one-page "Statement of Agreement," noting that "no other reports or statements [should] be considered as legislative history for the bill" and giving no insight into Congress' intentions beyond those listed as legislative findings in the first portion of the Act itself.⁹²

The Cholestin® decision was a dramatic setback to FDA's ability to regulate dietary supplements. This decision encourages manufacturers of dietary supplements to find and market "natural" substances, which are the active ingredients in prescription drugs, without going through the NDA process otherwise required. It is likely that such substances can be found, because many prescription drugs are derived from natural substances: digitalis is extracted from purple foxglove, morphine from poppy, and quinine from cinchona bark.⁹³ This interpretation essentially undercuts the entire NDA process. Prescription drug manufacturers can be expected to be less likely to pursue clinical trials and studies of medications derived from natural substances (or chemical substances that are indistinguishable from a natural substance), for fear that a dietary supplement could market the same product with less cost and less regulation.⁹⁴

This situation is harmful. The argument that "natural" substances are somehow safer than prescription drugs is undercut by the fact that many prescription drugs are derived from natural substances, as explained above, and yet are classified as prescription drugs. One of the reasons for strict regulation of prescription medications is the rigorous testing needed to ensure safety and efficacy. Another reason for a product

⁸⁹ *Id.* at *7.

⁹⁰ *Id.* at *2.

⁹¹ Indeed, James Rippe, Director of the Center for Clinical and Lifestyle Research (and co-chairman of the Pharmanex medical advisory board) argues that "[t]he Cholestin issue offers the clearest example that I have seen to date of accomplishing precisely what DSHEA intended, namely to encourage companies to seek natural products which have been in use for extended periods of time which could potentially result in health benefits." Allison Wright, *supra* note 70, at 9-10.

⁹² 1994 U.S.C.C.A.N. § 3523.

⁹³ Marcia Angell, M.D. & Jerome P. Kassirer, M.D., *Alternative Medicine — The Risks of Untested and Unregulated Remedies*, NEW ENG. J. MED., Sept. 17, 1999, at 839-41. Dr. Kessler, former Commissioner of FDA, noted in 1993 that approximately one-half of all drugs are derived from plants. See *Legislative Issues Related to the Regulation of Dietary Supplements: Hearing Before the Senate Labor & Human Resources Committee*, 103d Cong., 1st Sess., at 21 (statement of Dr. Kessler) (1994).

⁹⁴ Indeed, some of the biggest pharmaceutical companies are planning to sell their own herbal products, a possibility that concerns William B. Schultz, former FDA Deputy Commissioner for Policy. "If companies that would have tested their products and sold them as drugs are now going to not test them and sell them as dietary supplements, then we have lost information about the safety and efficacy of those products," Mr. Schultz notes. Sheryl Gay Stolberg, *Drug Regulators Make Push to Rein In Herbal Remedies*, N.Y. TIMES, June 10, 1998, at A1; *In the Wake of the Cholestin® Decision, Merck is Considering Asking the FDA for Permission to Switch Mevacor® to an OTC Product*, FOOD LABELING NEWS, Apr. 14, 1999, at 1064-6329.

to be regulated as a prescription medication (and not as a dietary supplement or an OTC product) is to provide an element of medical supervision. Many substances that have beneficial effects also have potentially negative side effects. In addition, some medications that are beneficial to individuals with a particular problem can be harmful to those that do not have the condition. For example, digitalin can be used to stimulate heart activity in individuals with congestive heart failure, a condition in which the heart is unable to sustain an adequate output to meet the body's needs.⁹⁵ If a person with a normal heart takes digitalis, however, it can result in irregular heartbeats and other adverse effects (including death).⁹⁶

Mevacor[®] itself provides an example of why physician supervision is needed. While lovastatin does lower cholesterol with relatively few side effects, it is contraindicated for women of childbearing age or pregnant women, because it has the potential to cause damage to the fetus.⁹⁷ According to the *Physicians' Desk Reference* (PDR) entry on Mevacor[®]/lovastatin:

. . . cholesterol and other products of the cholesterol biosynthesis pathway are essential components for fetal development. . . . Because of the ability of inhibits of MHG-CoA reductase such as MEVACOR to decrease the synthesis of cholesterol and possibly other products of the cholesterol biosynthesis pathway, MEVACOR is contraindicated during pregnancy and in nursing mothers. *MEVACOR should be administered to women of childbearing age only when such patients are highly unlikely to conceive.*⁹⁸

In addition, lovastatin can cause liver dysfunction in certain patients, and it is recommended that physicians carefully monitor patients who are taking both lovastatin and immunosuppressive drugs or lipid-lowering doses of nicotinic acid.⁹⁹ Because patients taking herbal remedies often assume they are safe and fail to inform their physician that they are ingesting these substances, the necessary physician monitoring is unlikely to occur in patients taking Cholestin[®], even though it seems virtually certain that the same risks exist.¹⁰⁰

FDA filed an appeal of the *Pharmanex* decision, and the issues were briefed in July 1999.¹⁰¹ In the interim, the agency may hope that other district courts will not follow the lead of the Utah court. If FDA's efforts to push their interpretation of dietary supplements is unsuccessful, however, there are relatively few regulatory options left open for the agency to address the safety problems posed. An examination of potential regulatory options available to FDA, using Cholestin[®] as an example and focusing on the potential for this product to harm a fetus should be illustrative.

⁹⁵ KURT J. ISSELBACHER ET AL., *HARRISON'S PRINCIPLES OF INTERNAL MEDICINE* 1005-06 (13th ed. 1994) (discussing control of heart failure with cardiac digitalis glycosides).

⁹⁶ See *supra* notes 72-75, and accompanying text. Adverse effects also can occur if an congestive heart failure patient takes too much digitalis, or if the patient has inadequate potassium levels in her blood.

⁹⁷ *PHYSICIANS' DESK REFERENCE* 1834-38 (47th ed. 1993).

⁹⁸ *Id.* at 1836 (emphasis in original).

⁹⁹ *Id.*

¹⁰⁰ Cholestin[®] is not the only herbal remedy that can create risks related to fertility and pregnancy. A recent study found that St. John's Wort, echinacea, and ginkgo biloba all had negative effects on eggs or sperm or both, and could interfere with conception or a healthy pregnancy. Jane E. Brody, *Herbal Remedies Tied to Pregnancy Risks*, N.Y. TIMES, Mar. 9, 1999, at F7. This article noted that "[d]espite the widespread belief, often fostered by advertising copy, that herbal preparations are 'natural' and 'drug-free,' those that have drug-like effects in the body do in fact contain potent chemicals that act like drugs." *Id.*

¹⁰¹ *FDA Tells Appeals Court that Cholestin is not a Dietary Supplement*, FOOD LABELING NEWS, July 28, 1999, at 1064-6329.

One possible regulatory option is to argue that the product is adulterated under section 402(f) of the FDCA, which provides that food is "adulterated" if it is a dietary supplement or contains a dietary ingredient that:

- (A) presents a significant or unreasonable risk of illness or injury under —
 - (i) conditions of use recommended or suggested in labeling, or
 - (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.¹⁰²

If the labeling of Cholestin® does not include a warning that pregnant women should not ingest the product, it is possible to argue that the product presents a "significant risk" that the fetus will suffer illness or injury. If it wished to make this argument, FDA would have to prove several different points. First, it would have to show that Cholestin® does present a significant risk of injury to the fetus. The scientific evidence on this point, while convincing enough to result in a contraindication warning for the prescription drug containing the same active ingredient, may not be sufficient to prove this for the dietary supplement. The PDR entry on Mevacor® notes that "lovastatin has been shown to produce skeletal malformations at plasma levels 40 times the human exposure (for mouse fetus) and 80 times the human exposure (for rat fetus),"¹⁰³ and that "reports of congenital anomalies have been received following intrauterine exposure to HMG-CoA reductase inhibitors."¹⁰⁴ A review of 100 pregnant women exposed to Mevacor® or a similar drug, however, showed that "the incidences of congenital anomalies, spontaneous abortions and fetal deaths/stillbirths did not exceed what would be expected in the general population."¹⁰⁵ Because safety has not been established, there is a risk of damage to the fetus, and there is "no apparent benefit" to treating pregnant women with lovastatin, the PDR recommends that "treatment should be immediately discontinued as soon as pregnancy is recognized."¹⁰⁶ It is not clear, however, whether this evidence would be sufficient to clearly show that this presents a "significant" risk of injury to the fetus.

This point draws attention yet again to the distinction between prescription drugs and dietary supplements. While the same evidence exists for the prescription drug form of lovastatin and the dietary supplement form of lovastatin, the existing regulatory structure ensures that one will be withheld from pregnant women while the other virtually will be unregulated.¹⁰⁷

Even if FDA were able to argue successfully that the evidence shows a significant risk to the fetus, it would face arguments that the language was intended to protect the individual taking the supplement (i.e., the pregnant woman, and not her fetus). Additionally, FDA would have to show that the conditions of use recommended in the labeling included pregnant woman.¹⁰⁸ If there were no conditions of use listed, to pre-

¹⁰² 21 U.S.C. § 342(f)(1)(A).

¹⁰³ PHYSICIANS' DESK REFERENCE, *supra* note 97, at 1838.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ While the PDR is not per se evidence of the existing medical standard, it seems extremely unlikely that a physician would prescribe a drug in a case where there is potential risk and no apparent benefit. A woman unaware of the studies showing potential risk, and reading only of the cholesterol-lowering benefits of Cholestin®, however, might decide to take the dietary supplement while pregnant.

¹⁰⁸ Based on the plain meaning of the rule, one could argue that, if the labeling language was "take one per day" and included no warning (such as "pregnant women should not take this product"), the conditions of use requirement would be met.

vail FDA would need to make the argument that "ordinary conditions of use" are such that pregnant women would consume sufficient amounts of the supplement to produce harm to the fetus.

Another regulatory option for FDA is to pass a regulation under the "misbranding" sections of the FDCA requiring that "information relating to" additional nutrients be included on the label. Food is "misbranded" under section 403(q)(1)(E) of the FDCA if its labeling does not comply with any regulation passed by FDA.¹⁰⁹ Section 403(q) of the FDCA allows FDA to pass regulations requiring any "other nutrient" be listed on the label of a food "if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices."¹¹⁰ FDA also can require that "information relating to such additional nutrient"¹¹¹ be included. Under those provisions, it is plausible that FDA could force Pharmanex to include information about lovastatin, including a pregnancy warning, on the label of Cholestin®, or to provide a package insert similar to those included with OTC drugs. The basis for this requirement would be that the pregnancy warning or insert explanation would be "information relating" to an additional nutrient in the food.¹¹² The additional nutrient (lovastatin) arguably could be required to be listed on the label once FDA determined that the listing of it would "assist consumers in maintaining healthy dietary practices."¹¹³

2. Benecol®: Dietary Supplement or Food?

Cholestin® is not the only dietary supplement that raises troubling definitional questions for FDA. McNeil Consumer Healthcare has announced its desire to market Benecol®, a margarine-like product made in Finland purported to lower cholesterol. Benecol®, unlike other margarine spreads, contains stanol ester, a derivative from wood and other plants that has been shown to prevent cholesterol from entering the bloodstream.¹¹⁴ If Benecol® is a dietary supplement, as the company claims, then FDA has limited regulatory authority. FDA, however, has taken the position that Benecol® is a food and that FDA has authority to determine the safety of stanol ester (under its food additives provisions) before allowing Benecol® to be marketed.¹¹⁵

B. Claims for Dietary Supplements: What Can Manufacturers Say?

The arguments over definition of supplements can be seen as the threshold argument of what claims can be put on particular products. The issues of definition and claims are intertwined: defining a product as a dietary supplement is important only because it allows various claims to be made without strict regulation, and the claims that are placed on a product determine whether it is a food/dietary supplement or a drug. Under DSHEA, dietary supplements can claim to affect the "structure or function" of the body, but cannot claim to cure, prevent, or treat any disease.¹¹⁶ This system

¹⁰⁹ 21 U.S.C. § 343(q)(1)(E).

¹¹⁰ *Id.*

¹¹¹ *Id.* § 343(q)(2)(A).

¹¹² *See id.*

¹¹³ *See id.* § 343(q)(1)(E).

¹¹⁴ *National Public Radio: Business: Domestic* (Morning Edition broadcast, Nov. 4 1998), available in 1998 WL 3309258; Harris, *supra* note 56, at 7.

¹¹⁵ *See National Public Radio: Business: Domestic*, *supra* note 114; Harris, *supra* note 56, at 7; *see also* Timothy Gower, *Rating the Cholesterol Busters*, HEALTH, Nov. 1, 1998, at 120, available in 1998 WL 14273576. For those who "can't wait" to get Benecol®, the compounds in it, phytosterol, are available in capsule form in health food stores and through mail-order firms. *Id.*

¹¹⁶ *See supra* notes 50-52, and accompanying text.

allows manufacturers of dietary supplements to hint that a product will help a disease without actually saying so (e.g., "lowers cholesterol" is reasonably understood by consumers to mean that the product treats the illness of high cholesterol).

1. FDA Regulation of Claims and the Pearson Decision

In April 1998, FDA proposed regulations on statements made for dietary supplements that were intended to give guidance on what types of statements were permissible structure/function claims and what types of statements were impermissible drug claims.¹¹⁷ In part, that proposed rule defined "disease" as "any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms."¹¹⁸ This proposed definition has created great controversy.¹¹⁹ Commentators have noted that "[t]here is no such thing as a normal body,"¹²⁰ and because "[v]irtually anything is a deviation from a normal body,"¹²¹ a literal interpretation of this definition would effectively mean that "there [is] no such thing as a structure/function claim" and that all claims are disease (drug) claims.¹²²

FDA Commissioner Dr. Jane Henney declared that she has not determined yet whether she agrees with this definition of disease, but notes the importance of settling "this key issue of 'disease,' for it is that definition that will guide the setting of the boundaries."¹²³ The controversy over the structure/function proposed rule essentially is a difference of opinion between those who feel that structure/function claims, which imply disease prevention and lead to consumers taking dietary supplements to prevent or cure disease are harmful,¹²⁴ and those who feel that "while some people might infer a disease-related claim from certain product labels, it is critical to permit helpful structure/function claims made in good faith."¹²⁵

¹¹⁷ Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,623 (Apr. 29, 1998) (to be codified at 21 C.F.R. pt. 101).

¹¹⁸ *Id.* at 23,625 (discussing proposed 21 C.F.R. § 101.93(g)(1)).

¹¹⁹ Between April 1998 and March 1999 FDA received more than 100,000 comments on the proposed rule, of which approximately 90% were critical. David Brown, *New FDA Commissioner Enters War Over Words*, WASH. POST, Mar. 26, 1999, at A31.

¹²⁰ Hutt, *supra* note 84, at 4-5.

¹²¹ *Id.*

¹²² *Id.* I. Scott Bass, an attorney for supplement manufacturers, argues that "[t]he way 'disease claim' is defined can make almost any health claim illegal." See Brown, *supra* note 119, at A31. At a March 25, 1999 hearing held by the U.S. House of Representatives Government Reform Committee, several of the industry representatives suggested that FDA should abandon its proposed rule because the rule would cover too many structure/function claims. See, e.g., I. Scott Bass, *Congressional Testimony of I. Scott Bass Before the Committee on Government Reform*, Mar. 25, 1999, available in 1999 WL 8082624; R. William Soller, *Testimony of R. William Soller, for the Consumer Healthcare Products Association Before the House Committee on Government Reform*, Mar. 25, 1999, available in 1999 WL 8086159; Annette Dickinson, *Testimony of Annette Dickinson, Ph.D., for the Scientific and Regulatory Affairs Council for Responsible Nutrition Before the House Committee on Government Reform*, Mar. 25, 1999, available in 1999 WL 8086158.

¹²³ Brown, *supra* note 119, at A31.

¹²⁴ See, e.g., Margaret Gilhooley, *Testimony of Prof. Margaret Gilhooley of Seton Hall Law School Before the House Committee on Government Reform on Dietary Supplements*, Mar. 25, 1999, available in 1999 WL 8086265. Prof. Gilhooley argues that the proposed FDA rules are too lenient. When a claim "relates to a matter beyond the ability of the consumer to assess from their own experience," she argues, there is great potential to mislead. *Id.* She argues for the position that "[p]roducts can be sold simply as dietary supplements, but when they go beyond that to make a structure and function claim, the statement should relate to the role of the dietary ingredient in the diet in achieving effects like those associated with the effects of foods. . . . For example, a supplement might claim that it provides energy, has a wake-up effect like coffee or a calming effect like tea." *Id.*

¹²⁵ I. Scott Bass, *supra* note 122. Mr. Bass argues that even "[i]f some people think that 'maintaining a good circulatory system' is an implied heart attack-prevention claim, that should not in itself make a structure/function claim illegal." *Id.*

The fact that the proposed rule accepts as non-drug claims statements such as "supports the immune system," "reduces stress and frustration," "helps maintain cardiovascular function," "improves absent-mindedness," "promotes relaxation," and "helps maintain regularity," shows how drastically the regulatory landscape has changed in recent years.¹²⁶ FDA currently faces the virtually impossible task of finding a rule that will satisfy both sides of this debate; while there are many industry representatives who oppose the proposed rule as overly stringent, several consumer groups feel that the rule does not go far enough.¹²⁷

FDA faces opposition to its restrictions on claims not only from industry and congressional sources, but also from the courts. A decision reached early in 1999 struck down FDA's efforts to restrict health claims on foods and dietary supplements under the NLEA, finding that First Amendment freedoms require the agency to be particularly careful in restricting manufacturers' ability to make supportable statements on their products' labels. In *Pearson v. Shalala*,¹²⁸ the D.C. Circuit Court reviewed a challenge by the American Preventive Medical Association and other appellants to FDA's final regulations promulgated under the NLEA.¹²⁹ Those regulations, which provide that a health claim can be made for either a food or a dietary supplement only if, based on the totality of publicly available scientific evidence, FDA determines that there is "significant scientific agreement" that the claim is supported by experts.¹³⁰ Using that standard, FDA has evaluated proposed health claims put forward by manufacturers of dietary supplements, including those in *Pearson*.¹³¹ FDA rejected these claims on the basis that the scientific evidence was inconclusive.¹³²

The court found that FDA's restrictions on commercial speech impermissible violated the First Amendment because the agency did not articulate a sufficient government interest in restricting the speech. Instead, the court found that the government's interest could be met by requiring a disclaimer under the claim, such as "[t]he evi-

¹²⁶ See 63 Fed. Reg. at 23,523; Hutt, *supra* note 84, at 6. Hutt notes that the above claims are "claims that five years ago would have gotten you into jail" and states that "[w]e have seen a revolution, which the dietary supplement industry does not fully realize." *Id.*

¹²⁷ See, e.g., *Justice Asks Court to Rehear Landmark Nutrition Labeling Case*, FDA WEEK, Mar. 26, 1999, at 4; see Gilhooley, *supra* note 124.

¹²⁸ 164 F.3d 650 (D.C. Cir. 1999).

¹²⁹ One should be clear that "health claims" are separate from "structure/function" claims. Under the FDCA, as amended by DSHEA, both foods and dietary supplements can make structure/function claims without being classified as a "drug." See 21 U.S.C. § 321(g)(1)(C) (defining "drug" as a article "other than food" which is "intended to affect the structure or any function of the body of man or other animals"); 21 U.S.C. § 343(r)(5)(D) (providing that a claim governed by § 343(r)(1)(B) (i.e., a statement which "characterizes the relationship of any nutrient [required by statute or FDA regulation to appear in the product's labeling] to a disease or a health-related condition") "shall be subject to a procedure the standard, respecting the validity of such claim, established by regulation of the Secretary"); 21 U.S.C. § 343(r)(6) (clarifying that a statement governed by § 343(r)(1)(B) may be made for a dietary supplement product if the statement "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans . . . or describes general well-being from consumption of a nutrient or dietary ingredient").

¹³⁰ Food Labeling Regulation, Amendment; Food Regulation Uniform Compliance Date; and New Dietary Ingredient Premarket Notification; Final Rules, 21 C.F.R. § 101.14(c).

¹³¹ Those claims include "consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers," "consumption of fiber may reduce the risk of colorectal cancer," "consumption of omega-3 fatty acids may reduce the risk of coronary heart disease," and ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." *Pearson*, 164 F.3d at 652.

¹³² *Id.* at 654. FDA has approved only two health claims for dietary supplements: one supporting the link between calcium and osteoporosis, 21 C.F.R. § 101.72(c)(2)(ii)(C), and one supporting the link between folate and neural tube defects, 21 C.F.R. § 101.79(c)(2)(ii)(B). In contrast, several health claims have been approved for foods, including one supporting the link between fiber and cancer. 21 C.F.R. § 101.76.

dence is inconclusive [on this claim]."¹³³ Furthermore, the court found that the standard "significant scientific agreement" was an insufficient explanation under the requirement that an agency not engage in arbitrary and capricious action.¹³⁴

While FDA is troubled by the implications of this ruling, further litigation of the case has been discouraged by some members of Congress. In a letter to the FDA Commissioner, a group of House Republicans requested "that the FDA spare the taxpayers the cost of further legal proceedings"¹³⁵ and instead simply approve the claims at issue in the case. Although FDA rejected this advice and asked for a rehearing of the case, the D.C. Court refused.¹³⁶

FDA is taking steps to maintain its ability to regulate claims for dietary supplements. Despite congressional opposition, FDA has persuaded the Department of Justice (DOJ) to seek a rehearing of the *Pearson* case.¹³⁷ The DOJ has requested that either the original three-judge panel, or an *en banc* panel, rehear the case, arguing that the ruling depended on "a misreading of Supreme Court commercial speech disclaimer precedents, none of which involved claims bearing on public health."¹³⁸ Furthermore, the DOJ argued that the decision "effectively deprives FDA of the well-settled power to define and apply regulatory provisions on a case-by-case basis."¹³⁹ FDA and the DOJ argue that if the decision stands, and dietary supplement manufacturers are allowed to label their products with sweeping health claims as long as they include a disclaimer, consumers will be unable to distinguish legitimate health claims from ones that are less well-founded.¹⁴⁰

While FDA waits to see whether the D.C. Circuit will reconsider its position on NLEA health claims, it also is considering the new rule on structure/function claims for dietary supplements, discussed above. As Commissioner Henney considers comments on the proposed rule, she also is considering establishing a panel, or a separate committee within FDA that would review dietary supplement labeling claims.¹⁴¹ FDA is planning to study consumer understanding of structure/function claims, focusing on whether consumers are able to distinguish structure/function claims from drug claims and whether consumers view dietary supplements (particularly botanicals) as more or less risky than OTC drugs.¹⁴² In addition to FDA's planned studies, other organizations have encouraged Congress to allocate funds to study dietary supplements.¹⁴³

FDA also has promulgated rules (first published in 1997 and effective as of March 1999) that require supplement manufacturers to print complete information on the

¹³³ 164 F.3d at 658.

¹³⁴ *Id.* at 660 (citing 5 U.S.C. § 706(2)(A) (1994)).

¹³⁵ FDA "Further Litigation" of *Pearson v. Shalala Discouraged by House GOPs*, F-D-C REP. ("The Tan Sheet"), Mar. 1, 1999, at 3.

¹³⁶ 172 F.3d 72 (D.C. Cir. 1999).

¹³⁷ *Justice Asks Court to Rehear Landmark Nutrition Labeling Case*, FDA WEEK, Mar. 26, 1999, at 22.

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ "Having lost confidence in all claims, consumers would be less likely to adopt healthier dietary practices, ultimately increasing their risk of disease and preventable death," argued the Department of Justice in its petition for rehearing. *Id.*

¹⁴¹ *FDA Considers Setting Up Panel to Review Dietary Supplement Claims*, FDA WEEK, Mar. 26, 1999, at 1.

¹⁴² *FDA to Study Consumer Perception of Structure/Function Claims*, FDA WEEK, Mar. 12, 1999, at 1.

¹⁴³ The National Institutes of Health requested that its budget for fiscal year 2000 include \$50.2 million to fund research on dietary supplements and alternative medicine. *NIH Officials Brief Congressional Panel on White House Request for \$50.2 Million for Alternative Medicine Research*, FOOD CHEMICAL NEWS, Mar. 15, 1999, available in 1999 WL 9625453. This money would be used by the National Center for Complementary and Alternative Medicine. One of the Center's first priorities is to study the efficacy of ginkgo biloba as a treatment for dementia. *Id.*

labels of their products.¹⁴⁴ The "Supplement Facts" panel must list: suggested serving size, information on nutrients "present in significant levels;" the percent Daily Value (of the Recommended Daily Allowance) where applicable, and "all other dietary ingredients present in the product."¹⁴⁵

2. *The FTC's Role in Regulating Claims*

Consumers concerned about misleading or untruthful information about dietary supplements may be comforted partly by the role of the FTC in regulating dietary supplement advertising. The FTC has the authority to prevent companies from making false and unsubstantiated statements about their products in advertisements, and recently issued advertising guidelines intended to prevent false or misleading claims about dietary supplements.¹⁴⁶ Presumably, at least the more egregious dietary supplement claims are caught by the FTC's watchful eye. For example, the FTC recently brought an action against Rose Creek Health Products, maker of "Vitamin O."¹⁴⁷ "Vitamin O," according to its advertising, addresses the problem of "oxygen deficiency" by allowing oxygen molecules to be absorbed through the gastrointestinal system upon oral administration of the product.¹⁴⁸ The FTC filed a complaint against the company in U.S. District Court for the Eastern District of Washington on March 11, 1999.¹⁴⁹ Then in April, U.S. District Court Judge Edward Shea granted FDA's request for a preliminary injunction limiting how Rose Creek could market "Vitamin O." The FTC has taken similar actions in the past against dietary supplement manufacturers who make unfounded claims.¹⁵⁰

The FTC's jurisdiction is limited. The FTC regulates product advertising and ensures the advertising is "truthful and not misleading" and that any statement made has "adequate" substantiation of its truth.¹⁵¹ The FTC, however, does not address safety issues such as whether the manufacturer has provided adequate information about the product's health risks, nor can the FTC (or, under current law, FDA) force a manufacturer to test a product to ensure that it is safe at the recommended dose and under the recommended conditions.

3. *Purity and Consistency*

FDA is attempting to grapple with the purity and consistency problems associated with dietary supplements by proposing good manufacturing practices (GMPs)

¹⁴⁴ U.S. Department of Health and Human Services, *Dietary Supplements Now Labeled with More Information*, Mar. 23, 1999 (press release), (visited Nov. 18, 1999) <www.fda.gov/bbs/topics/NEWS/NEW00678.html>. *Food Labeling: Nutrition Labeling of Dietary Supplements on a "Per Day" Basis*, 64 Fed. Reg. 1765 (codified at 21 C.F.R. pt. 101).

¹⁴⁵ *Id.*

¹⁴⁶ See Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry*, (1998) (visited Nov. 18, 1998), <www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>.

¹⁴⁷ U.S. FTC: *FTC Charges Marketer of "Vitamin O" With Making False Health Claims*, M2 PRESSWIRE, Mar. 16, 1999, available in 1999 WL 140641239.

¹⁴⁸ "Mighty 'Vitamin O'," BIO/TECH NEWS (1998). This publication, touting "Inside Information" on the product was mailed out to potential consumers. Testimonials in the advertising materials suggest that the product effectively treats cancer, and will help breathing problems, headaches, infections, colds, and the flu.

¹⁴⁹ According to independent laboratory analysis, however, the product is nothing more than salt water. Claire Martin, *The O Hype "Vitamin O" Elixir Just Salt Water by Analysis*, DENVER POST, Apr. 13, 1999, at E1; U.S. FTC *supra* note 146; Mike Roarke, *Ruling Hasn't Killed Vitamin O Sales*, SPOKANE SPOKESMAN-REV., Apr. 30, 1999, at A16.

¹⁵⁰ For example, in 1998, the FTC forced New Vision International, Inc. to stop making claims that its supplement could cure conditions such as Attention Deficit Disorder. The supplement, called "God's Cocktail," contained a mixture of minerals, anti-oxidants, and alfalfa sprouts. Harris, *supra* note 56, at 5.

¹⁵¹ *Id.*

and developing an adverse events reporting system. DSHEA provided explicit authority for FDA to create GMPs, and FDA published an Amended Notice of Proposed Rulemaking (ANPR) in February 1997.¹⁵² The ANPR set out the dietary supplement industry's proposed GMPs and requested comments on that submission and on the need for and ways to develop acceptable GMPs. Over two years have passed since the comment deadline for this ANPR, and it seems that FDA will soon propose a GMP rule for dietary supplements.¹⁵³

FDA also has developed programs through which consumers can report their experiences of any adverse effects from dietary supplements. FDA's web page cites several ways a consumer can report "a problem or illness caused by a Dietary Supplement."¹⁵⁴ Health professionals are encouraged to monitor and report adverse events and product problems through FDA's "meditate" program.¹⁵⁵ In 1998, reports of ill effects stemming from dietary supplements, compiled by FDA's Office of Special Nutritional Adverse Event Reporting System, were placed on the website, providing consumers greater access to information about potentially problematic products, but also opening FDA to criticism that it has adopted a "guilty until proven innocent" standard for dietary supplement manufacturers.¹⁵⁶

VII. CONCLUSION AND RECOMMENDATIONS

FDA is attempting to effectively and fairly regulate dietary supplements. The current congressional climate, however, is skeptical of FDA regulation. As noted above, members of Congress have discouraged FDA from further pursuing appeals of adverse court rulings, while other members are critical of FDA's proposed rule on structure/function claims.¹⁵⁷ In addition, legislative proposals offered in the 106th Congress would ease governmental regulation and oversight of dietary supplements, while expanding patient access to these products. One such proposal would ensure that Medicare and Medicaid would cover payments for dietary supplements.¹⁵⁸

This legislative climate of skepticism of any increased regulation continues despite evidence that the public would prefer greater regulation of dietary supplements and more government involvement in the study of whether such products are safe and effective. A recent study performed by National Public Radio, the Kaiser Foundation, and the Kennedy School of Government suggests that many consumers feel there is insufficient regulation of the safety and purity of supplements.¹⁵⁹ Many consumers

¹⁵² 108 Stat. 4325, 4331 (DSHEA § 9) (adding 21 U.S.C. § 342(g)). Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements, 62 Fed. Reg. 5699 (Feb. 6, 1997).

¹⁵³ See Henney, *supra* note 56, at 3-4.

¹⁵⁴ See Food & Drug Admin., Center for Food Safety and Applied Nutrition, *Overview of Dietary Supplements* (visited Mar. 24, 1999) <vm.cfsan.fda.gov/~dms/ds-oview.html>.

¹⁵⁵ See, e.g., Food & Drug Admin., *Meditate: The FDA Medical Products Reporting Program* (visited Apr. 19, 1999) <www.fda.gov/medwatch>.

¹⁵⁶ See Annette Dickinson, *supra* note 122. Dr. Dickinson notes that "a company can find itself in the position of having its company name and brand associated with a serious adverse event posted on the Web without having any prior warning . . . [and] the background information on the case is unlikely to be available under FOIA [the Freedom of Information Act], because FDA does not have adequate staff to purge personal care information not releasable [sic] under FOIA." *Id.* She further notes that because of minimal FDA resources, the agency has limited ability to properly investigate and evaluate complaints. *Id.*

¹⁵⁷ At the March 25, 1999 congressional hearing, Government Affairs Committee Chairman Dan Burton (R-IN) noted that "the proposed rule does not comply with the legislation." *FDA Considers Setting up Panel to Review Dietary Supplement Claims*, FDA WEEK, Mar. 26, 1999, at 4.

¹⁵⁸ Harris, *supra* note 56.

¹⁵⁹ NPR Poll, *supra* note 68, at question 15. Of those polled, 59% felt that there was "not as much [regulation] as there should be" to ensure that supplements "don't harm people who use them," and 60% felt that there

also want more government regulation to "make sure that health claims made in advertisements for these supplements are true."¹⁶⁰

The lack of laws that would allow consumers to distinguish safe and effective supplements from those that are benign but useless or harmful is disappointing, especially in light of the fact that many of the alternative medicines, including supplement usage, show great potential for helping both minor and major ailments.¹⁶¹ As long as the effective products are sold alongside (and often with labels identical to) useless or harmful products, and as long as the available information includes only "studies" conducted by those with a financial interest in the product, neither consumers nor medical professionals can be confident in the use of most supplements. Instead of encouraging health care professionals to promote the use of these potentially useful supplements, the unscientific and lax approach to regulating the supplements is antagonizing and alienating such professionals and creating a break-down of communication between doctor and patient. While there is some reliable information available about the safety and efficiency of various dietary supplements, the vast majority of consumers interested in using such supplements appear to receive their information from "product labels, health-food store salespeople, or friends."¹⁶²

FDA is doing what it can to ensure the safety, if not the effectiveness, of supplement products, but when the laws require them to act only when they have information that a supplement actually is dangerous (rather than testing whether it is dangerous before allowing consumers to take it), there only is so much the agency can do. Given the current climate, it is unlikely that the situation will change greatly until there is a public outcry for Congress to adjust the laws. And it is unlikely that a public outcry will occur absent some catastrophic adverse reaction to a supplement or other major event.¹⁶³

What could be done to ameliorate the situation? A good solution would work to ensure safety and efficacy of dietary supplements, and also ensure the availability of helpful products without the long delay or price increases that seem likely to accompany premarket screening. This paper offers one compromise solution. Let all manufacturers of dietary supplements pay a small tax — some minor percentage of their profits — to finance an FDA report which will be available publicly and offered to

was "not as much [regulation] as there should be" to ensure that "these supplements are pure and their dosages are consistent." *Id.* 24% and 23%, respectively, responded that the current regulations were the "right amount" of regulation, and 7% and 6%, respectively, felt that there was currently "too much regulation." *Id.*

¹⁶⁰ *Id.*, at question 15-c.

¹⁶¹ For example, a recent *Journal of the American Medical Association* edition devoted to alternative medicine published studies showing: that "moxibustion (stimulation of an acupuncture point by heat generated from burning a specific herb) is helpful for correction of breech presentation in late pregnancy," that a "Chinese herbal medicine formulation improves symptoms of irritable bowel syndrome"; and that saw palmetto extracts "improve urologic symptoms in patients with benign prostatic hyperplasia." Francesco Cardini, M.D. & Huang Weixin, M.D., *Moxibustion for Correction of Breech Presentation*, JAMA, Nov. 11, 1998, at 1580; Alan Bensoussan, M.Sc. et al., *Treatment of Irritable Bowel Syndrome with Chinese Herbal Medicine: A Randomized Controlled Trial*, JAMA, Nov. 11, 1998, at 1585; Timothy J. Wilt, M.D., M.P.H. et al., *Saw Palmetto Extracts for Treatment of Benign Prostatic Hyperplasia*, JAMA, Nov. 11, 1998, at 1604.

¹⁶² Kathleen Doheny, *The Road Less Traveled*, SHAPE, May 1999, at 55. Medical Economics, the company responsible for publishing the well-known *Physicians' Desk Reference*, recently published THE PHYSICIANS' DESK REFERENCE FOR HERBAL MEDICINES (1998), which offers information on more than 600 herbs. This publication relies in large part on information from the German Regulatory Authority's Commission E, the agency in Germany responsible for safeguarding herbal medicine, and on the results of an international literature review.

¹⁶³ "People drink their herbal tea with ginseng or whatever, and they think 'what's the harm with nutritional supplements like this? Well, in large part, we don't know,'" says Linda Golodner, President of the National Consumers League. Ms. Golodner adds that "[w]e don't want consumers to be guinea pigs." Harris, *supra* note 56. At the moment, however, that is exactly what they are.

consumers, free of charge, wherever dietary supplements are sold. This report would offer objective study and analysis of dietary supplements and would list those supplements that have been proven safe and effective for particular problems.

This solution would discourage irresponsible marketing of products, which manufacturers know to be unsafe or ineffective, and would encourage companies to fund objective studies that would be accepted by FDA as sufficient proof of safety and efficacy. Contrast this commercial incentive for objective studies with the current language requiring that materials accompanying a product must simply present a "balanced view of the *available* scientific information," a standard which makes no requirement that the available information be credible.¹⁶⁴ The information would allow consumers to choose to purchase those supplements proven safe and effective, but would not restrict their freedom to purchase other supplements if they wish to do so.

This solution is a compromise between the premarket approval model rejected by Congress and the current policing model in which FDA only has the power to remove those products which it can affirmatively prove are dangerous. FDA would retain the ability to remove dangerous products, and simply would be providing additional information to consumers.¹⁶⁵ This plan effectively would divide the available products into three classes: 1) those proven safe, or safe and effective, which would be listed in the FDA publication; 2) those proven unsafe, which would be removed by FDA; 3) those about which sufficient information is not yet available, which would be available for purchase at the consumer's risk. The list could also provide information about certain companies or brands that have shown that they repeatedly meet standards of consistency and purity in their products, as part of the safety evaluation. And it could inform consumers that certain products only should be taken under physician supervision, and/or that certain products should not be taken by individuals with certain conditions (e.g., pregnancy).

This solution appears to strike a balance between goals of consumer protection, availability of information and potentially helpful products, and would provide effective market incentives toward those goals. As stated above, however, it will be difficult to convince Congress of the need for changes in the direction of safety and protection, absent some well-publicized consumer tragedy. It is unfortunate that consumers should be required to wait for a catastrophe to create sound policy.

¹⁶⁴ 108 Stat. 4329 (DSHEA § 5); 21 U.S.C. § 343B(a)(3) (emphasis added).

¹⁶⁵ This strategy also avoids the current judicial concern about conflicts between the First Amendment and FDA's traditional posture of controlling information about products regulated by the agency.